



IFW

Docket No. 2609/68585-A/JPW/GJG/JBC/MML/SK

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants : Daniella Licht et al.
Serial No. : 10/773,472
Filed : February 5, 2004
Title : SUSTAINED RELEASE FORMULATION OF N-(2-
PROPYLPENTANOYL)GLYCINAMIDE AND RELATED
COMPOUNDS

1185 Avenue of the Americas
New York, New York 10036
June 22, 2004

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

INFORMATION DISCLOSURE STATEMENT

In accordance with their duty of disclosure under 37 C.F.R. §1.56, applicants direct the Examiner's attention to the following documents which are listed on Form PTO-1449 (**Exhibit A**) and are also listed below.

Pursuant to the Notice appearing in the August 5, 2003 Official Gazette, because this application was filed after June 30, 2003, copies of the U.S. Patents and U.S. Patent Application Publications listed herein are not provided.

This Information Disclosure Statement is being submitted pursuant to 37 C.F.R. §1.97(b)(3) before the mailing of a first Office Action on the merits. Thus, this Information Disclosure Statement should be entered and considered. Copies of the

Applicants: Daniella Licht et al.
Serial No.: 10/773,472
Filed: February 5, 2004
Page 2

documents listed below as items 4, 14-21 are attached hereto as
Exhibits 1-9:

1. U.S. Patent No. 4,301,176, issued November 17, 1981 to Grabowski et al.;
2. U.S. Patent No. 4,699,927, issued October 13, 1987, to Deboeck;
3. U.S. Patent No. 4,913,906, issued April 3, 1990, to Friedman et al.;
4. Reexamination Certificate of U.S. Patent No. 4,913,906, issued June 6, 2000 (**Exhibit 1**);
5. U.S. Patent No. 5,009,897, issued April 23, 1991, to Brinker et al.;
6. U.S. Patent No. 5,169,642, issued December 8, 1992, to Brinker et al.;
7. U.S. Patent No. 5,585,358, issued December 17, 1996, to Bialer et al.;
8. U.S. Patent No. 6,054,461, issued April 25, 2000, to Fairbanks et al.;
9. U.S. Patent No. 6,319,903 issued November 20, 2001, to Carrazana et al.;

Applicants: Daniella L. Hnt et al.
Serial No.: 10/773,472
Filed: February 5, 2004
Page 3

10. U.S. Patent No. 6,419,953, issued July 16, 2002, to Qiu et al.;
11. U.S. Patent No. 6,555,585, issued April 29, 2003, to Shirvan et al.;
12. U.S. Patent No. 6,720,004, issued April 13, 2004, to Qui et al.;
13. U.S. Application Publication No. US 2002-0052418, published May 2, 2002, Shirvan et al.;
14. European Patent No. 0 814 789, published January 7, 1998 (**Exhibit 2**);
15. PCT International Application Publication No. WO 95/01956, published January 19, 1995 (**Exhibit 3**);
16. PCT International Application Publication No. WO 02/13766, published February 21, 2001 (**Exhibit 4**);
17. PCT International Application Publication No. WO 02/07677, published January 31, 2002 (**Exhibit 5**);
18. Attal N. et al., (1999) Mechanism of action and rationale for use of antiepileptic drugs. International Congress and Symposium Series, No. 241, The Royal Society of Medicine Press, Limited Ed. JM Pellock (**Exhibit 6**);

Applicants: Daniella Licht et al.
Serial No.: 10/773,472
Filed: February 5, 2004
Page 4

19. Bialer M. (1992) Pharmacokinetic evaluation of sustained release formulations of antiepileptic drugs. Clinical implications. Clin. Pharmacokinet., 22(1):11-24 (**Exhibit 7**);
20. Blotnick et al., (1997) The Disposition of Valproyl Glycinamide and Valproyl Glycine in Rats. Pharmaceutical Research, 14(7):873-8 (**Exhibit 8**); and
21. The Merck Manual of Diagnosis and Therapy, 16th Ed., pp. 1407-26 (**Exhibit 9**).

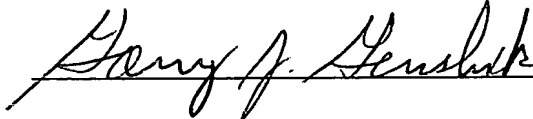
Applicants request that the Examiner review the references and make them of record in the subject application.

If a telephone interview would be of assistance in advancing prosecution of the subject application, applicants' undersigned attorney invites the Examiner to telephone him at the number provided below.

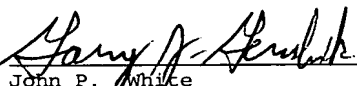
Applicants: Daniella D. H. et al.
Serial No.: 10/773,472
Filed: February 5, 2004
Page 5

No fee is deemed necessary in connection with the filing of this Information Disclosure Statement. However, if any fee is required, authorization is hereby given to charge the amount of any such fee to Deposit Account No. 03-3125.

Respectfully submitted,



I hereby certify that this correspondence is being deposited this date with the U.S. Postal Service with sufficient postage as first class mail in an envelope addressed to:
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

 6/22/04
John P. White Date
Reg. No. 28,678
Gary J. Gershik
Reg. No. 39,992

John P. White
Registration No. 28,678
Gary J. Gershik
Registration No. 39,992
Attorneys for Applicants
Cooper & Dunham LLP
1185 Avenue of the Americas
New York, New York 10036
(212) 278-0400



PTO-1449		U.S. Department of Commerce Patent and Trademark Office		Atty. Docket No. 68585-A/JPW/GJG/JBC		Serial No. 10/773,472						
INFORMATION DISCLOSURE CITATION (Use several sheets if necessary)				Applicants: Daniella Licht et al.								
				Filing Date February 5, 2004		Group						
U.S. PATENT DOCUMENTS												
Examiner Initial	Document Number			Date	Name	Class	Subclass	Filing Date if Appropriate				
	4	3	0	1	1	7	6	11/17/81	Grabowski et al.			
	4	6	9	9	9	2	7	10/13/87	Deboeck			
	4	9	1	3	9	0	6	4/3/90	Friedman et al.;			
	5	0	0	9	8	9	7	4/23/91	Brinker et al.;			
	5	1	6	9	6	4	2	12/8/92	Brinker et al.;			
	5	5	8	5	3	5	8	12/17/96	Bialer et al.;			
	6	0	5	4	4	6	1	4/25/00	Fairbanks et al.;			
	6	3	1	9	9	0	3	11/20/01	Carrazana et al.;			
	6	4	1	9	9	5	3	7/16/02	Qiu et al.;			
	6	5	5	5	5	8	5	7/16/02	Shirvan et al.;			
	6	7	2	0	0	0	4	4/13/04	Qui et al.;			
	20	02	00	52	4	1	8	5/2/02	Shirvan et al.;			
FOREIGN PATENT DOCUMENTS												
	Document Number			Date	Country	Class	Subclass	Translation				
								Yes	No			
	EPO	0	8	1	4	7	8	9	1/7/98	EPO;		
	WO	9	5	0	1	9	5	6	1/19/95	PCT;		
	WO	0	2	1	3	7	6	6	2/21/01	PCT;		
	WO	0	2	0	7	6	7	7	1/31/02	PCT;		
OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)												
Reexamination Certificate of U.S. Patent No. 4,913,906, issued June 6, 2000;												
Attal N. et al., (1999) Mechanism of action and rationale for use of antiepileptic drugs. <u>International Congress and Symposium Series</u> , No. 241, The Royal Society of Medicine Press, Limited Ed. JM Pellock ;												
Bialer M. (1992) Pharmacokinetic evaluation of sustained release formulations of antiepileptic drugs. Clinical implications. <u>Clin. Pharmacokinet.</u> , 22(1):11-24;												
Blotnick et al., (1997) The Disposition of Valproyl Glycinamide and Valproyl Glycine in Rats. <u>Pharmaceutical Research</u> , 14(7):873-8; and												
The Merck Manual of Diagnosis and Therapy, 16 th Ed., pp. 1407-26 .												
EXAMINER						DATE CONSIDERED						
<p>*EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP 609: Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.</p>												

Applicants: Daniella Licht et al.
 Serial No.: 10/773,442
 Filed: February 5, 2004
 Exhibit A